IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: STEINMAN=1B

In re Application of:	)	Conf. No.: 5046
	)	
Lawrence STEINMAN	)	Art Unit: 1617
	)	
Appln. No.: 09/719,770	)	Examiner: J. Kim
	)	
Filed: September 6, 2001	)	Washington, D.C.
	)	
For: METHOD AND COMPOSITIONS FOR TREATING DISEASES MEDIATED BY ...	)	January 10, 2003

RESPONSE

Honorable Commissioner for Patents
Washington, D.C. 20231

Sir:

The present communication is responsive to the official action of December 12, 2002. Claims 1-8, 15 and 16 presently appear in this case. No claims have yet been examined on the merits. All of the claims have been subject to restriction requirement. Reconsideration and withdrawal of the restriction requirement and action on all of the claims now present in the case are respectfully urged.

The examiner states that the present application contains the following inventions that are not so linked as to form a single general inventive concept:

Group I, including claims 2, 3 and 8, drawn to a method of treating neurodegenerative disease by administering a transglutaminase inhibitor;

Group II, including claims 4, 5 and 8, drawn to a method of treating a cell-mediated autoimmune disease by administering a transglutaminase inhibitor; and

Group III, including clams 6-8, drawn to a method of treating an inflammatory disease of the central nervous system by administering a transglutaminase inhibitor.

The examiner states that the inventions do not relate to a single general concept as they lack the same or corresponding special technical feature because the various diseases are not related to one another and have different known etiology. Accordingly, applicant has been required to elect a single invention of Groups I-III. The examiner notes that claims 1, 15 and 16 are generic and will be examined with an elected group. This restriction requirement is respectfully traversed.

First of all, in order to be responsive, applicant hereby elects Group I, drawn to a method of treating neurodegenerative disease by administering a transglutaminase inhibitor and presently comprising claims 1-3, 8, 15 and 16.

The present restriction requirement is respectfully traversed because it is not in accordance with the

instructions concerning unity of invention appearing in Annex B of the PCT Administrative Instructions, Part I, "Instructions Concerning Unity of Invention". Similar language also appears at MPEP §1850. At both places it states:

> Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims.

Later, it states at Section (c)(i) in Annex B of the PCT Administrative Instructions and in the first paragraph of the right-hand column of page 1800-61, in MPEP §1850, Revision of August 2001:

> Equally, no problem arises in the case of genus/species situation where the genus claim avoids the prior art.

Here, claim 1 is a true genus claim. It is not written in Markush group language. The examiner has not taken the position that claim 1 is unpatentable over the prior art. Accordingly, as claim 1 is a true genus claim, it is inappropriate for the examiner to require restriction among the dependent claims. Respectfully, the examiner is not following the procedure required by the MPEP and the Administrative Instructions under the PCT which governs national phase applications, such as the present. Thus, as long as claim 1 is patentable over the prior art, all of the dependent claims must be examined.

Furthermore, the examiner is incorrect in stating that all of the three diseases have different known etiologies. The common technical feature shared by all three sets of claims is that each of the diseases is mediated by transglutaminase. Therefore, even in the absence of an allowable generic claim, the three species of disease share a special technical feature in the fact that they are all mediated by transglutaminase and, therefore, all can be treated by a transglutaminase inhibitor. For this reason as well, the restriction requirement is improper and should be withdrawn.

Accordingly, reconsideration and examination of all of the claims now present in the case are earnestly solicited.

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Lawrence STEINMAN

Application No.: 09/719,770 Conf. No.5046

Filed: September 6, 2002

For: METHOD AND COMPOSITIONS FOR TREATING DISEASES MEDIATED BY ...

Art Unit: 1617

Examiner: J. Kim

Washington, D.C.

Atty.'s Docket: STEINMAN=1B

Date: January 10, 2003

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith is a [ ] Amendment [X] Response

in the above-identified application.

[XX] Small Entity Status: Applicant(s) claim small entity status. See 37 C.F.R. §1.27.

[XX] No additional fee is required.

[ ] The fee has been calculated as shown below:

	(Col. 1) CLAIMS REMAINING AFTER AMENDMENT		(Col. 2) HIGHEST NO. PREVIOUSLY PAID FOR	(Col. 3) PRESENT EXTRA EQUALS	SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
TOTAL	*	MINUS	** 20	0	x 9	$		x 18	$
INDEP.	*	MINUS	*** 3	0	x 42	$		x 84	$
FIRST PRESENTATION OF MULTIPLE DEP. CLAIM					+ 140	$		+ 280	$
					ADDITIONAL FEE TOTAL	$	OR	TOTAL	$

* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.

** If the "Highest Number Previously Paid for" IN THIS SPACE is less than 20, write "20" in this space.

*** If the "Highest Number Previously Paid for" IN THIS SPACE is less than 3, write "3" in this space.

The "Highest Number Previously Paid For" (total or independent) is the highest number found from the equivalent box in Col. 1 of a prior amendment of the number of claims originally filed.

[XX] Conditional Petition for Extension of Time

If any extension of time for a response is required, applicant requests that this be considered a petition therefor.

[ ] It is hereby petitioned for an extension of time in accordance with 37 CFR 1.136(a). The appropriate fee required by 37 CFR 1.17 is calculated as shown below:

Small Entity			Other Than Small Entity		
Response Filed Within			Response Filed Within		
[ ]	First	- $ 55.00	[ ]	First	- $ 110.00
[ ]	Second	- $ 205.00	[ ]	Second	- $ 410.00
[ ]	Third	- $ 465.00	[ ]	Third	- $ 930.00
[ ]	Fourth	- $ 725.00	[ ]	Fourth	- $ 1450.00
Month After Time Period Set			Month After Time Period Set		

[ ] Less fees ($_____) already paid for ___ month(s) extension of time on _____.

[ ] Please charge my Deposit Account No. 02-4035 in the amount of $_____.

[ ] Credit Card Payment Form, PTO-2038, is attached, authorizing payment in the amount of $_____.

[ ] A check in the amount of $_____ is attached (check no.).

[XX] The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035. This authorization and request is not limited to payment of all fees associated with this communication, including any Extension of Time fee, not covered by check or specific authorization, but is also intended to include all fees for the presentation of extra claims under 37 CFR §1.16 and all patent processing fees under 37 CFR §1.17 throughout the prosecution of the case. This blanket authorization does not include patent issue fees under 37 CFR §1.18.

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